

**REGISTRATION REPORT
Part B**

**Section 1: Identity, physical and chemical
properties, other information**

Detailed summary of the risk assessment

Product code: Serenade SC
Active Substance: 13.96 g/L - $1,0 \times 10^9$ CFU/g
Bacillus subtilis QST 713

Central Zone
Zonal Rapporteur Member State: The Netherlands

CORE ASSESSMENT

Applicant: Bayer CropScience SA-NV
Date: January 2016



M-504642-02-1

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Introduction

This document reviews the information related to the identity, the physical, biological and chemical properties, the data on application and further information for the microbial plant protection product for the microbial plant protection product Serenade SC containing *Bacillus subtilis* strain QST 713. Inclusion of *B. subtilis* QST 713 into Annex I of 91/414/EEC (now list of approved active substances according to (EU) No 540/2011) entered into force in February 2007 (Commission Directive 2007/6/EC¹). *B. subtilis* strain QST 713 was notified and defended by AgraQuest Inc. Bayer CropScience AG, the applicant for registration of Serenade SC in the Central European zone, holds a Letter of Access for all active substance and product data. The formulation Serenade SC was not the representative formulation in the dossier for Annex I inclusion of *B. subtilis* QST 713 and has not been previously evaluated according to Uniform Principles.

This document refers to the conclusions of the EU review of *B. subtilis* QST 713. The active substance data is relied upon in the risk assessment of the formulation Serenade SC.

Note: this Part B document only reviews data (Annex II and Annex III) and additional information that have not previously been considered within the EU review process, as part of the Annex I inclusion decision. New Annex II data will only be included if they are considered essential for the evaluation and in this case a full study summary will be provided. In the case where the formulation has been previously evaluated, at the European level, detailed summaries have not been provided.

The Annex I Inclusion Directive for *B. subtilis* QST 713 (Commission Directive 2007/6/EC¹) provides specific provisions under Part B, which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation:

- For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on the active substance *B. subtilis* QST 713 (SANCO/10184/2003) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Information on the detailed composition of Serenade SC can be found in the confidential dossier of this submission (Registration Report - Part C).

Serenade SC is a biological fungicide and bactericide formulated as suspension concentrate. The content of the active ingredient *B. subtilis* QST 713 in Serenade SC is 1.34% (w/w). Assuming a density of 1.042 kg/L this corresponds to 13.96 g/L. The minimum content of viable spores of *B. subtilis* QST 713 in Serenade SC is 1×10^{12} CFU/kg (or 1.042×10^{12} CFU/L).

With regard to safety issues, it is important to note that *B. subtilis* is naturally present in our environment. Therefore, its application in control of plant pathogenic fungi means only a fluctuation of the bacterium population in the biotope of the target pathogen and does not disturb the natural micro-flora. The experience that *B. subtilis* QST 713 presents no risk for humans, animals and the environment has been confirmed by numerous studies.

¹ OJ L 43, 15.02.2007

INTRODUCTION ON THE IDENTITY OF THE MICROBIAL PEST CONTROL AGENT

The review report for *B. subtilis* QST 713 (SANCO/10184/2003 - final – 14/07/2006) is considered to provide the relevant review information or a reference to where such information can be found. The data presented in the present dossier comply with the agreed end points in the Review Report. The representative formulation in the EU review was Serenade WP.

The following table provides the EU endpoints to be used in the evaluation as summarised in the SANCO report for *Bacillus subtilis* QST 713 (SANCO/10184/2003 - final – 14/07/2006).

Agreed EU End-points: *Bacillus subtilis* QST 713 (SANCO/10184/2003 - final – 14/07/2006).

EU End-Point	Active Substance <i>Bacillus subtilis</i> , strain QST 713
Purity of active substance ²	No relevant impurities
Intended Uses:	Biological fungicide and bactericide
Known or new organism:	Existing organism
GMO	No genetic modification
Taxonomy:	Family: Bacillaceae Genus: <i>Bacillus</i>
Species, subspecies, strain:	<i>Bacillus subtilis</i> (Cohn 1872), strain QST 713
Origin of the isolate / Culture collection / Identification:	<i>B. subtilis</i> QST 713 was isolated from soil in a peach tree orchard in Fresno County, California (USA) in 1995. The strain QST 713 (identical with strain AQ 713) is deposited in the Agricultural Research Culture Collection (NRRL), Illinois, USA, under the reference number NRRL B-21661. Using the available morphological, physiological and biochemical data, the strain QST 713 was clearly identified as <i>Bacillus subtilis</i> . Besides the basically relevant positive Catalase reaction inherent to all <i>Bacillus</i> species, further biochemical key parameters identifying strain QST 713 as <i>B. subtilis</i> are e.g.: positive Voges-Proskauer reaction and growth in 7 % NaCl. Strain discrimination of <i>Bacillus subtilis</i> QST 713 is possible by ribotyping.
Method of analysis:	The species is identified by microscopy using classical morphological (cellular and colonial morphology) criteria and by using physiological and biochemical criteria.
Mode of action:	The mode of action of <i>B. subtilis</i> is fungistatic and fungitoxic by disruption of hyphae following contact with the fungal pathogen at the leaf surface. Besides antagonism nutrient competition is involved in the mode of action and more importantly <i>B. subtilis</i> induces systemic resistance response of the plant, indicated by enhanced peroxidase production.

² According to Commission Directive 2008/113/EC (OJ L 330, 09.12.2008, p.6)

EU End-Point	Active Substance <i>Bacillus subtilis</i> , strain QST 713
Life cycle:	All spore-formers, including members of the genus <i>Bacillus</i> , undergo a cycle consisting of several discernible phases: germination, outgrowth, multiplication, and sporulation. The primary cell formed at the end of outgrowth can, under some conditions, such as insufficient nutrients, divide asymmetrically and proceed directly to sporulation or, in time of favourable conditions, such as sufficient nutrients, can divide symmetrically and proceed through many divisions before sporulating. The endospore plays a dominant role in the biology and the life-cycle of <i>B. subtilis</i> and relatives. It is a dormant structure which enables the micro-organism to survive when environmental conditions turn unfavourable for vegetative growth and is a vehicle for dispersal by dust and air streams, as it is easily blown up. The global distribution of <i>Bacillus</i> spp. may largely be derived from the endospore-forming capability. Basically, the endospore is the most heat tolerant bacterial lifeform, enduring temperatures >80°C or even >100°C. The endospore does not present an obligate stage in the life-cycle, vegetative growth by cell-division may be predominant – or even the norm, unless e.g. lack of nutrients occurs. In a dry state endospores can remain viable for several years.
Natural occurrence:	<i>B. subtilis</i> is prevalent in all environmental compartments, occurring mainly in the form of viable spores. Occurrence of the species is not geographically restricted. Levels of bacilli
Host specificity:	<i>B. subtilis</i> is not characterised by a distinct host specificity since growth is not dependent upon a host but upon supply with decomposable organic matter.
Known opportunist:	<i>B. subtilis</i> is considered an opportunist with no pathogenic potential. In some cases <i>B. subtilis</i> was isolated from surgical wounds or tumour drainages; only highly immunosuppressed patients were reported to have suffered from dissipating infections.
Toxin production:	<i>B. subtilis</i> produces different exo-enzymes contributing to the decay of organic matter. The extracellular enzyme subtilisin is known to elicit allergic or hypersensitive reactions in individuals repeatedly exposed to it. However, its toxigenic properties are assessed to be very low. There is no evidence for production of toxins. <i>B. subtilis</i> is generally considered to have a low degree of virulence to humans.
Resistance:	Up to now there is no indication of decreasing efficacy of the <i>B. subtilis</i> QST 713 against fungal pathogens to be controlled. The mode of action of <i>B. subtilis</i> QST 713 has been demonstrated to rely on a broader base than single site action, since it includes diverging mechanisms not easily to overcome by pathogens. The risk on the occurrence of development of resistance is to be classified as low.
Resting stages:	Spore forming

EU End-Point	Active Substance <i>Bacillus subtilis</i>, strain QST 713
Production control:	Each "seed" (liquid media with suspended cells) transfer is checked for purity both microscopically and by streak plating. The completed fermentation material (broth) of each fermentation run (batch) is tested by counts of colony forming units (CFU) of <i>B. subtilis</i> , microscopic examination, optical density and is tested for contaminants by plating analysis, esp. with regard to human pathogens.

IIIM 1 IDENTITY OF THE MICROBIAL PEST CONTROL PRODUCT

Please also refer to introduction above.

IIIM 1.1 Applicant (name, address, contact, telephone and telefax number)

Name Bayer CropScience SA-NV
Person to contact: Sara Trsinar
Address Development & Registration
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The Netherlands
Phone +31 (0)297 280255
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IIIM 1.2 Manufacturer(s) of the preparation and producer of the microbial pest control agent

IIIM 1.2.1 Manufacturer(s) of the preparation (name, address, contact, telephone and telefax numbers)

Name Bayer CropScience AG
Person to contact: Sherry D. Heins
Address 890 Embarcadero Drive,
West Sacramento
CA 95605 U.S.A.
Phone +1 (916) 661-3307 direct
FAX +1 (916) 661-3001
e-mail sherry.heins@bayer.com

Location of the manufacturing site(s):

CONFIDENTIAL information – data provided separately (Part C).

IIIM 1.2.2 Producer of the microbial pest control agent (name, address, contact, telephone and telefax numbers)

Identical to Point IIIM 1.2.1

Location of the manufacturing site(s):

CONFIDENTIAL information – data provided separately (Part C).

IIIM 1.3 Trade name or proposed trade name and manufacturers code number(s), for the preparation and similar preparations (differences to be specified)

Trade Name: Serenade SC

IIIM 1.4 Placeholder**IIIM 1.5 Physical state of MPCP (crop life formulation type)**

Suspension Concentrate [Code: SC]

IIIM 1.6 Function (herbicide, insecticide, etc.)

Biological fungicide and bactericide

IIIM 1.6.1 Biological function category and field of use category, using terms defined by each country, e.g. “control of weeds” for “forestry”

Function: Serenade SC acts as microbial fungicide and bactericide.

Field of use: Agriculture, horticulture, professional use.

IIIM 1.7 Other/special studies

No additional issues have been identified that might require special studies.

IIIM 1.7.1 Concentration of MPCA in MPCP, measured in terms of g/kg or g/L of the MPCP and in cfu’s or other appropriate potency units; provide content of MPCA in technical grade of MPCA, in the same terms

The content of the active ingredient *B. subtilis* QST 713 in Serenade SC is 1.34% (w/w, 13.96 g/L) corresponding to a minimum content of 1×10^{12} CFU/kg (1.042×10^{12} CFU/L).

IIIM 1.7.1.1 Also indicate: scientific name and strain/serotype of MPCA, its accession number in a recognised culture collection

Strain	QST 713
Species	<i>Bacillus subtilis</i>
Genus	<i>Bacillus</i>
Family	Bacillaceae
Order	Bacilliales
Class	Bacilli
Phylum	Firmicutes
Domain	Bacteria

The strain QST 713 has been added to the internationally accepted Agriculture Research Culture Collection (NRRL), Illinois, USA, code number NRRL B-21661.

IIIM 1.7.1.2 Also indicate: development phase (e.g. spore) of MPCA in MPCP

The development phase of the MPCA in the formulated product are viable spores.

IIIM 1.7.2 Composition in terms of g/kg or g/L and % w/w of each ingredient in MPCP

CONFIDENTIAL information – data provided separately (Part C, Point IIIM 1.7.2).

IIIM 1.7.3 Quality criteria for the production and storage of the MPCP

CONFIDENTIAL information – data provided separately (Part C, Point IIIM 1.7.3).

IIIM 1.7.4 Quality control data (measures of quality criteria) from 3-5 production

batches

CONFIDENTIAL information – data provided separately (Part C, Point IIIM 1.7.4).

IIIM 1.7.5 The formation and/or impact of unintentional ingredients

CONFIDENTIAL information – data provided separately (Part C, Point IIIM 1.7.2).

IIIM 2 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE MICROBIAL PEST CONTROL PRODUCT

Physical, chemical and technical properties are reported in the following table:

Test or study & Annex point	Guideline and Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
IIIM2.2	Low temperature storage stability study (7 days storage at 0°C).					
	Visual and smelling control of the test item. CIPAC MT 39.3	Serenade SC batch no. LJSB000445 (1.5×10^{10} CFU/g)	Low temperature storage stability study (7 days storage at 0°C). ca. 4% light brown, clear liquid phase on top after warming up to ambient temperature, completely reversible after 1 inversion	Y	Wiese, W. Beyer, M.	Acceptable Phase separation is reversible after warming up to ambient temperature, therefore no problems are expected.
	suspensibility, CIPAC MT 184		0.27 % in CIPAC standard water D before and after storage: 100 % 8 % in CIPAC standard water D before and after storage: 99 %	Y		
	wet sieve test CIPAC MT 185		Before storage: 0.07% residue on 75 µm sieve After storage: 0.08% residue on 75 µm sieve	Y		
IIIM 2.3	Explosivity, oxidising properties, flash point, flammability, spontaneous ignition, acidity, alkalinity, pH, viscosity, surface tension					
Explosivity, oxidising properties	(EC) No 440/2008 A.14 OCSPP.6316	Serenade SC batch no. LJSB000445 (1.5×10^{10} CFU/g)	Not explosive	Y	Keldenich, 2015 (KIIM 2.3.1/01)	Acceptable
IIIM 2.3.1	(EC) No. 440/2008, A.21		No oxidizing properties	Y		

Test or study & Annex point	Guideline and Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
IIIM2.2	Low temperature storage stability study (7 days storage at 0°C).					
Flash point, flammability, spontaneous ignition	(EC) No 440/2008 A. 14 DIN EN ISO 2719 OCSP 830.6316	Serenade SC batch no. LJSB000445 (1.5×10^{10} CFU/g)	No flash point up to 91 °C	Y	Keldenich, 2015 (KIIIM 2.3.2/01)	Acceptable
IIIM 2.3.2	(EC) No 440/2008 A. 15 DIN 51794		Auto-Ignition temperature 475 °	Y		
Acidity, alkalinity, pH IIIM 2.3.3	CIPAC MT 75.3 OCSP 830.7000	Serenade SC batch no. 2015-003712 (9.8×10^9 CFU/g)	pH-value Undiluted: 5.3 1% in deionised water: 5.5	Y	Schumacher and Beyer, 2015 (KIIIM 2.2/05)	Acceptable
Persistent foaming III 2.4.2	CIPAC MT 47.2	Serenade SC batch no. 2015-003712 (9.8×10^9 CFU/g)	Persistent foaming 8% in CIPAC standard water D foam after 10 s: 16 mL foam after 1 min: 12 mL foam after 3 min: 10 mL foam after 12 min: 6 mL	N	Schumacher and Beyer, 2015 (KIIIM 2.2/05)	Acceptable
Suspensibility, suspension stability IIIM 2.4.3	CIPAC MT 184 Bacillus subtilis	Serenade SC batch no. 2015-003712 (9.8×10^9 CFU/g)	Suspensibility (biological assay) 0.27% in CIPAC standard water D 100% 8% in CIPAC standard water D 99%	N	Schumacher and Beyer, 2015 (KIIIM 2.2/05)	Acceptable

Test or study & Annex point	Guideline and Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
IIIM2.2	Low temperature storage stability study (7 days storage at 0°C).					
Spontaneity	CIPAC MT 160	Serenade SC batch no. 2015-003712 (9.8 x 10 ⁹ CFU/g)	Spontaneity (gravimetical assay) 5% in CIPAC water D102%	N	Schumacher and Beyer, 2015 (KIIM 2.2/05)	Acceptable

IIM 2.7 Summary and evaluation of data on properties of the MPCP

All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. Serenade SC is a light brown, opaque liquid, suspension concentrate formulation with a sourly odour. It is not explosive, oxidizing or highly flammable and it has a neat pH of 5.3, in a 1% aqueous solution it has a pH value of 5.5. No loss of efficacy is noted when Serenade SC is stored for 2 years at 20°C and for 18 weeks at 40°C in HDPE. The product does separate 0°C, but this process is reversible when the product is warmed to ambient temperature..

In conclusion, the physical, chemical and technical properties of Serenade SC indicate that no particular problems are to be expected when it is used as recommended.

Implications for labelling: None

IIM 3 DATA ON APPLICATION

IIM 3.1 Pest to be controlled, crop to be protected, available information on mode of action

The product Serenade SC will be used against different plant pathogenic fungi in fruits, vegetables and grapes. Please, refer to Appendix 2 for further details. The mode of action of *Bacillus subtilis* QST 713 was described in detail in Annex II, Doc IIM, Section 1, Point IIM 2.3.2. of the EU dossier This information also applies to the formulation Serenade SC. *B. subtilis* QST 713 prevents plant diseases by first creating a zone of inhibition on the leaf and preventing attachment and penetration of the pathogens. Growth of the pathogens is stopped by outcompeting for nutrients and space on the leaf. Furthermore, three groups of lipopeptides are produced (iturins, agrastatins/plipastatins, and surfactins) that synergize each other to destroy germ tubes and mycelia of pathogenic fungi by puncturing their cell membranes. When the appressorium is killed, and spore germination is stopped, the infection is stopped and disease is prevented from spreading to the rest of the plant. Furthermore, *Bacillus subtilis* induces the systemic resistance response of the plant, indicated by enhanced peroxidase activity. This mechanism is also relevant for the activity against the bacterial infection fire blight caused by *Erwinia amylovora*.

Details of intended use

Serenade SC was recently authorised in the Netherlands. The application dossier was submitted to Slovenia as zonal rapporteur member state for the assessment of Serenade SC in member states of the Central European zone (outdoor use) or member states of all three EU evaluation zones (protected crops).

In the Netherlands an authorisation was granted for the following uses:

- strawberry (protected), for the control of *Botrytis cinerea*
- carrots (field), for the control of *Alternaria dauci*.
- strawberry (field) and grapes (field) for the control of *Botrytis cinerea* and lettuce (protected and field) for the control of *Botrytis cinerea* and *Sclerotinia sclerotiorum* as minor use.

An authorisation could not be granted for the following uses:

- fruiting vegetables of Solanaceae (protected crops), for the control of *Botrytis cinerea*
- carrots (field), for the control of *Erysiphe heraclei*.

This evaluation concerns an extension of the authorisation of Serenade SC for the control of powdery mildew (*Oidium lycopersici*) in protected fruiting vegetables of Solanaceae in the Netherlands.

Please, refer to Appendix 2 for further details.

IIM 3.2 Available information on the development of resistance in target pest and

appropriate mitigation strategy

For detailed information on the possible formation of resistance in target species to *Bacillus subtilis* strain QST 713, refer to Annex II, Doc IIM, Section 1, Point IIM 3.6 in the EU dossier.

Development of resistance depends on the mode of action. The more specific the action and the biochemical target site, with a few or single gene(s) being involved, the more probable is development of resistance. *B. subtilis* QST 713 attacks the disease at multiple sites, so that the risk of developing resistance is rather low.

Until now, there has been no indication of decreasing efficacy of *B. subtilis* QST 713 against the target pathogens.

IIM 3.3 Application rate in terms of mass/vol of MPCP per unit area /volume. Content of micro-organism in material used

Serenade SC (13.4 g/kg, min. 1×10^{12} CFU/kg) is to be applied at amounts of 8 L product/ha. The product should be diluted in 600 - 3000 L water/ha, depending on the crop and its development stage. Thus, the concentration of micro-organism in the spray solution is normally in the range between 0.0112 and 0.056 kg/hL corresponding to 8.33×10^{11} – 4.17×10^{12} CFU/hL. For further details, please refer to Appendix 2, Table of Good Agricultural Practice.

IIM 3.4 Application rate in terms of units of micro-organism per unit area/volume

The maximum application rate of Serenade SC are 8 L/ha. In terms of units of micro-organism per ha this is 0.112 kg/ha corresponding to 8.34×10^{12} CFU/ha.

IIM 3.5 Method of application (incl. type of equipment and volume of diluent)

The product is applied by foliar or high vegetation spraying, depending on the crop. This may be done e.g. by tractor mounted boom or by knapsack sprayers. The volume of diluent spray amounts to 600 - 3000 L water/ha.

IIM 3.6 Number, timing and conditions of applications

IIM 3.6.1 Number, timing and conditions of applications, related to: host/pest phenology, duration of protection, application of other pesticides.

Serenade SC should be applied whenever the above mentioned plant pathogenic fungi are a problem, ideally prior to or in the early stages of disease development. It can be applied throughout the growing season, with up to nine applications per season. The minimum interval between applications is five days. For further details, please refer to Appendix 2, Table of Good Agricultural Practice.

Serenade SC may be applied alone or in a spraying sequence including other pesticides. Mixtures with products attacking organic material are to be avoided.

IIM 3.6.2 Pre-harvest interval.

Due to the low toxicity and the fast degradation of *B. subtilis* by UV light, a pre-harvest interval is not required.

IIM 3.7 Precautions to avoid phytotoxic/phytopathogenic effects on protected crop or on succeeding crops, if appropriate

Not required. *B. subtilis* is not expected to show phytotoxic or phytopathogenic effects on crops.

IIM 3.8 Proposed instructions for use as printed, or to be printed, on labels

Serenade SC is for control of grey mould in strawberry crops, leaf blight on carrots, and powdery mildew on tomatoes, pepper and aubergine.

Mixing and Spraying

Before use ensure that all spray equipment is clean. Add half the volume of water required, and start agitating. Agitate product container well and add the required amount of Serenade SC to the tank, while filling the spray tank with the required volume of water. Keep agitating until spraying completed. All application equipment must be thoroughly cleaned with water prior to storage or use on another crop. Serenade SC should be applied in sufficient water to ensure good crop cover, according to the GAP table presented above. For further information, please refer to the label submitted in KIIM 3.8/01.

IIIM 4 APPLICATION INSTRUCTIONS, PRECAUTIONS, CLEANING FOR THE MICROBIAL PEST CONTROL PRODUCT

IIIM 4.1 Packaging description

Serenade SC is packaged according to the following specification:

Dimensions of the primary packaging – “2.5 gal. (10 L) jerrican”:

type:	jerrican with screw cap
material:	63 mm Universal CR, HDPE (High Density Polyethylene), white, density 2, pcf class 250
weight:	455 ± 5 g (tolerance -5/+10 g)
weight cap:	24.5 ± 1 g
height:	373 ± 5 mm
length:	233 ± 5 mm
width:	181 ± 5 mm
content:	10 L
∅ internal neck:	48 ± 0.5 mm
∅ external on strings:	59.7 + 0.5 / - 0.3 cm
colour:	White MB-28

Dimensions (internal) of the secondary packaging:

type:	box containing 2 primary packagings
material:	B C flute (double wall)
length:	388 mm
width:	238 mm
height:	375 mm
colour:	white

QRD 288 master shipping unit (pallet with 36 units of the secondary packaging):

weight:	approximately 805 kg
length:	121.9 cm (48”)
width:	101.6 cm (40”)
height:	133 cm

For further information please refer to documents submitted in KIIM 4.1/01 to 4.1/03.

IIIM 4.2 Specifications of packaging and measures of its suitability

Taking into account the composition of the product and its anticipated physical properties, Serenade SC is characterized as non-reactive. The chemically inert product does not require special stability or resistance properties of the packaging or the material used for its transport. Nonetheless, further investigations and tests were conducted by the supplier, attesting for the suitability of the packaging characteristics. Please refer to documents submitted in KIII 4.1/01 and KIII 4.1/03.

IIIM 4.3 Label instructions: cleaning equipment and protective clothing

Please refer to Point IIIM 4.4.

IIIM 4.4 Procedures to clean equipment and protective clothing

Equipment cleaning procedure

Rinse spray tank with water and distribute the cleaning water on the treated area, or dispose it according to local ordinances.

If Serenade SC has been tank-mixed with other registered pesticides, rinse tank with an appropriate product, usually alkaline based, to neutralize any remaining product(s) residue and spray out onto the crop or dispose according to local ordinances.

For further information, please refer to the label submitted in KIIM 4.4/01.

Protective clothing cleaning procedure

Protective clothing shall be washed in the usual way.

IIIM 4.5 Necessary waiting periods for re-entry

Pre-harvest interval for each relevant crop:

Serenade SC is not supposed to produce any relevant residues on the crop. *B. subtilis* QST 713 does not produce toxins or secondary metabolites of toxic concern for non-target organisms, including man and domestic animals. Fixing a pre-harvest interval is therefore not relevant.

Re-entry period for livestock, to areas to be grazed:

Not relevant (see above). Serenade SC is not intended for use on pastures.

Re-entry period for man to crops, buildings or spaces treated:

Not relevant (see above).

Withholding periods for animal feeding stuffs

Not relevant (see above).

Waiting period between application and handling treated products

Not relevant (see above).

Waiting period between last application and sowing or planting succeeding crops.

B. subtilis does not cause injuries to plants. Due to restricted field persistence and absence of toxicity, waiting periods for planting or sowing of succeeding crops are not required.

Information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used

None of the test results obtained or observations made were such that restrictions need to be imposed.

IIIM 4.6 Label instructions regarding: safe handling and storage

Please refer to Point IIIM 4.7.

IIIM 4.7 Recommendations regarding: handling, storage, transport, fire: specify risks, specify procedures to minimize hazards and the generation of waste

Handling:

No special measures necessary if stored and handled correctly. Ensure thorough ventilation of stores and work areas. When using do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift.

Storage:

Segregate from foods and animal feeds. Further information on storage conditions: Keep away from heat. Protect from direct sunlight. Storage stability: Storage duration: 24 Months

Transport: There are no restrictions regarding transport of Serenade SC on land or sea since neither the ingredients nor the formulated end product have corrosive, reactive or flammable properties.

Fire: Suitable extinguishing media: water spray, carbon dioxide, foam, dry powder.

Special hazards arising from the product: Carbon monoxide, carbon dioxide, nitrogen oxides
The substances/groups of substances mentioned can be released in case of fire.

Advice for fire-fighters, Special protective equipment:

Wear self-contained breathing apparatus and chemical-protective clothing.

Further information:

In case of fire and/or explosion do not breathe fumes. Keep containers cool by spraying with water if exposed to fire. Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

Procedures to minimize the generation of waste Contaminated packaging:
Contaminated packaging should be emptied as far as possible and disposed of in the same manner as the substance/product.

Hazardous combustion products: Reactivity: No hazardous reactions if stored and handled as prescribed/indicated.
Chemical stability: The product is stable if stored and handled as prescribed/indicated.

Possibility of hazardous reactions: No hazardous reactions if stored and handled as prescribed/indicated.

Incompatible materials: Substances to avoid are strong oxidizing agents, strong bases, strong acids

Please, for any further information refer to the Material Safety Data Sheet submitted in KIIM 4.7/01.

IIIM 4.8 Label instructions regarding: cleanup of spills

Please refer to Point IIIM 4.9.

IIIM 4.9 Detailed procedures in case of accident to: contain a spill, decontaminate an area or vehicle, dispose of adsorbents and packaging, protect workers and bystanders, first aid

Disposal of damaged packaging, adsorbents and other materials: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or disposal program (often such programs are run by state or local governments or by industry).
Since containers are nonrefillable, do not reuse or refill them. Follow label instruction for cleaning and disposal.

<u>Personal precautions, protective equipment and emergency procedures</u>	Do not breathe vapour/spray. Use personal protective clothing. Avoid contact with the skin, eyes and clothing.
<u>Environmental precautions</u>	Do not discharge into the subsoil/soil. Do not discharge into drains/surface waters/groundwater.
<u>Methods and material for containment, cleaning up and decontamination</u>	For small amounts: Pick up with suitable absorbent material (e.g. sand, sawdust, general-purpose binder, kieselguhr). For large amounts: Dike spillage. Pump off product. Dispose of absorbed material in accordance with regulations. Collect waste in suitable containers, which can be labelled and sealed. Clean contaminated floors and objects thoroughly with water and detergents, observing environmental regulations.
<u>Protection of emergency workers:</u>	Respiratory protection: not required. Hand protection: Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) and other. Eye protection: Safety glasses with side-shields (frame goggles) (e.g. EN 166) Body protection: Body protection must be chosen depending on activity and possible exposure, e.g. apron, protecting boots, chemical-protection suit (according to EN 14605 in case of splashes or EN ISO 13982 in case of dust). General safety and hygiene measures: The statements on personal protective equipment in the instructions for use apply when handling crop-protection agents in final-consumer packing. Wearing of closed work clothing is recommended. Store work clothing separately. Keep away from food, drink and animal feeding stuffs.
<u>First aid measures:</u>	Remove contaminated clothing. If inhaled: Keep patient calm, remove to fresh air. On skin contact: Wash thoroughly with soap and water. On contact with eyes: Wash affected eyes for at least 15 minutes under running water with eyelids held open. On ingestion: Rinse mouth and then drink plenty of water. Most important symptoms and effects, both acute and delayed Symptoms: No significant reaction of the human body to the product known.

For any further information please refer to the Material Safety Data Sheet submitted in KIIM 4.9/01.

IIIM 4.10 Procedures for destruction/disposal of MPCP and its packaging (e.g. Detailed instructions for controlled incineration)

Please refer to IIIM 4.7.

IIIM 4.10.1 Controlled incineration

Must be sent to a suitable incineration plant, observing local regulations.

IIIM 4.10.2 Methods other than controlled incineration

Not applicable.

IIIM 4.11 Further information**IIIM 4.11.1 Information of authorisations in other countries**

Serenade SC is already registered in the UK (registration number: 15625) and in Ireland (registration number: 03847). Other products containing *B. subtilis* QST 713 as active ingredient are already registered in Slovenia, Germany, Switzerland, France, Portugal and Italy since several years (refer to table below).

Country	Product name	Registration number
Ireland	Serenade SC	03847
UK	Serenade SC	14318 and 15625
Slovenia	Serenade WP	3433-63/09/02
Germany	Serenade MAX	006388-00
Switzerland	Serenade Max	W-6678
	Serenade WPO	W-6682
France	Serenade Biofungicide	2050001
	Serenade Jardins	2110040
	Serenade MAX	2100162
Portugal	Serenade MAX	0267
Italy	Serenade MAX	12628
	Serenade NATRIA	15298

IIIM 4.11.2 Information on established Maximum Residue Limits (MRL) in other countries

In compliance with Commission Regulation (EC) No 149/2008 an MRL is not required for *B. subtilis* QST 713.

IIIM 4.11.3 Justified proposals for classification and labelling

No classification is required with regard to physical/chemical, toxicological, environmental or ecotoxicological properties of the product. The following labelling is required due to a possible sensitizing potential of the active ingredient contained in Serenade SC.

Bacillus subtilis QST 713 may have the potential to provoke sensitizing reactions.

IIIM 4.11.4 Proposals for risk and safety phrases

Risk phrases are not required.

The following safety phrases are proposed:

S2: Keep out of the reach of children.

S13: Keep away from food, drink and animal feeding stuffs.

S20/21: When using do not eat, drink or smoke.

IIIM 4.11.5 Proposed label

Refer to draft label provided in KIIM 3.8.

IIIM 4.11.6 Specimens of proposed packaging

Will be provided on request.

Appendix 1: List of data submitted in support of the evaluation

dRR Annex point/ reference number	Author(s)	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protec-tion claimed yes/no	Study relied on Y/N	Dataprot ection granted Y/N	Owner
KIIM 2.2/05	Wiese, W. Beyer, M.	2015	Cold stability of Bacillus subtilis QST713 SC (Serenade ASO) Bayer CropScience AG Study ID. FM0265(ACR17)N01	yes	Y	Y	BCS
KIIM 2.3.1/01	Keldenich, H.P.	2015	Safety relevant data of Bacillus subtilis QST713 SC (Serenade ASO) Bayer Technology Services GmbH Report-no. M-525556-01-1 GLP: yes Published: no	yes	Y	Y	BCS
KIIM 2.3.2/02	Keldenich, H.P.	2015	Safety relevant data of Bacillus subtilis QST713 SC (Serenade ASO) Bayer Technology Services GmbH Report-no. M-525556-01-1 GLP: yes Published: no	yes	Y	Y	BCS
KIIM 2.4/05	Schumacher, R., Beyer, M.	2015	Physical, chemical and technical properties of Bacillus subtilis QST713 SC Bayer CropScience AG Report no. FM0265(PCF00)G01 GLP: yes Published: no	yes	Y	Y	BCS

dRR Annex point/ reference number	Author(s)	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protec-tion claimed yes/no	Study relied on Y/N	Dataprot ection granted Y/N	Owner
KIIIM 4.1/03	Ochoa Campos, M.,A.	1900	TECHNICAL SPECIFICATION MECHANICAL DRAWING P00197 - AgraQuest, Inc. Report-no. not stated GLP/GEP: no Published: no	yes	N	N	QST
KIIIM 4.7/01	Anonymous	2013	BASF SAFETY DATA SHEET: SERENADE ASO - BASF AG Report-no. 394711/SDS_CPA_EU/EN GLP/GEP: no Published: no	yes	N	N	BAS

Appendix 2: Critical Uses – justification and GAP tables

Serenade SC

PPP (product name/code)	Serenade SC	Formulation type:	Suspension concentrate (SC)
Active substance 1	<i>Bacillus subtilis</i> QST 713	Conc. of as 1:	13.96 g/L, 1.042×10^{12} CFU/L (13.4 g/kg, 1×10^{12} CFU/kg)
Active substance 2	-	Conc. of as 2:	-
Active substance	-	Conc. of as:	-
Safener	-	Conc. of safener:	-
Synergist	-	Conc. of synergist:	-
Applicant:	Bayer CropScience SA-NV	Professional use	<input checked="" type="checkbox"/>
Zone(s):	Central EU	Non professional use	<input type="checkbox"/>
Verified by MS:	no		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	NL	Fruiting vegetables of <i>Solanaceae</i> (tomatoes, pepper, aubergine)	G	<i>Oidium lycopersici</i>	Spraying	BBCH 21 – 89 Jan-Dec	9 (5 days)	a) 8 b) 72	a) 0.112 b) 1.008	600-3000	Not relevant	-
2	NL	Chicory (roots)	F	<i>Sclerotinia sclerotiorum</i> , <i>Alternaria</i> Spp. <i>Erysiphales</i>	Spraying	BBCH 12-49 Jun-Oct	6 (5 days)	a) 8 b) 48	a) 0.112 b) 0.672	150-400	Not relevant	Minor use
3	NL	Wild chicory	F	<i>Sclerotinia sclerotiorum</i> , <i>Alternaria</i> Spp. <i>Erysiphales</i>	Spraying	BBCH 12-49 Jun-Oct	6 (5 days)	a) 8 b) 48	a) 0.112 b) 0.672	150-400	Not relevant	Minor use
4	NL	Weld, quinoa, sorghum	F	<i>Sclerotinia sclerotiorum</i> , <i>Alternaria</i> Spp. <i>Erysiphales</i>	Spraying	BBCH 12-49 Jun-Oct	6 (5 days)	a) 8 b) 48	a) 0.112 b) 0.672	150-400	Not relevant	Minor use
5	NL	Pomes	F	<i>Erwinia amylovora</i>	Spraying	BBCH 51-85 April-Oct	9 (5 days)	a) 8 b) 72	a) 0.112 b) 1.008	200-1500	Not relevant	Minor use
6	NL	Drupes	F	<i>Pseudomonas syringae</i>	Spraying	BBCH 51-85 April-Oct	6 (5 days)	a) 8 b) 48	a) 0.112 b) 0.672	200-1500	Not relevant	Minor use
7	NL	Drupes	G	<i>Pseudomonas syringae</i>	Spraying	BBCH 51-85 April-Aug	6 (5 days)	a) 8 b) 48	a) 0.112 b) 0.672	200-1500	Not relevant	Minor use
8	NL	Nuts	F	<i>Xanthomonas campestris</i> pv. <i>Juglandis</i> <i>Pseudomonas syringae</i> pv. <i>aesculi</i>	Spraying	BBCH 51-85 April-Oct	9 (5 days)	a) 8 b) 72	a) 0.112 b) 1.008	200-1500	Not relevant	Minor use
9	NL	Fruiting vegetables of Cucurbits with edible peel)	G	<i>Botrytis cinerea</i> <i>Sphaerotheca fuliginea</i>	Spraying	BBCH 12-89 All year	9 (5 days) per crop cycle 27 per year	a) 8 b) 72 (per crop) 216 (per year)	a) 0.112 b) 1.008 (per crop) 3.024 (per year)	600-3000	Not relevant	Minor use

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
10	NL	Fruiting vegetables of Cucurbits with non-edible peel)	G	<i>Botrytis cinerea</i> <i>Sphaerotheca fuliginea</i>	Spraying	BBCH 12-89 All year	9 (5 days) per crop cycle 27 per year	a) 8 b) 72 (per crop) 216 (per year)	a) 0.112 b) 1.008 (per crop) 3.024 (per year)	600-3000	Not relevant	Minor use
11	NL	Heading cabbage	F	<i>Xanthomonas campestris</i> <i>pv. campestris</i>	Spraying	BBCH 12-49 Jun-Oct	6 (5 days)	a) 8 b) 48	a) 0.112 b) 0.672	200-800	Not relevant	Minor use
12	NL	Cauliflower family	F	<i>Xanthomonas campestris</i> <i>pv. campestris</i>	Spraying	BBCH 12-49 Jun-Oct	6 (5 days)	a) 8 b) 48	a) 0.112 b) 0.672	200-800	Not relevant	Minor use
13	NL	Asparagus	F	<i>Botrytis cinerea</i>	Spraying	BBCH 12-49 Jun-Oct	6 (5 days)	a) 8 b) 48	a) 0.112 b) 0.672	500-800	Not relevant	Minor use
14	NL	Stalk celery	F	<i>Septoria apicola</i>	Spraying	BBCH 12-49 Apr-Oct	6 (5 days)	a) 8 b) 48	a) 0.112 b) 0.672	150-400	Not relevant	Minor use
15	NL	Tree nursery crops	F	<i>Bacterial diseases</i> (<i>Erwinia</i> , <i>Pseudomonas</i> , <i>Xanthomonas</i>)	Spraying	BBCH 12-89 March-Oct	9 (5 days)	a) 8 b) 72	a) 0.112 b) 1.008	200-1200	Not relevant	Minor use